PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (see an example) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Introduction effects of the Australian plain packaging policy on adult
	smokers: Cross-sectional study
AUTHORS	Wakefield, Melanie; Hayes, Linda; Durkin, Sarah; Borland, Ron

VERSION 1 - REVIEW

REVIEWER	Olivia Maynard PhD student Tobacco and Alcohol Research Group School of Experimental Psychology University of Bristol UK
REVIEW RETURNED	No competing interests. 21-May-2013

THE STUDY No supplementary files included. 1. P.8. The statistical analyses section is unclear and it is not determine how the different analyses conducted (logistic regr and ANCOVA) relate to the results. Correcting for differences between individuals who have perhaps made a choice to smo from plain over branded packaging is important, so make it cl how these covariates were chosen. If BMJ Open permit it, it r make this easier to understand for the reader, if the results from logistic regression (third paragraph of results section), were not to the statistical analysis section? Also, which covariates were ultimately chosen might be better placed before the discussion.	
determine how the different analyses conducted (logistic regrand ANCOVA) relate to the results. Correcting for differences between individuals who have perhaps made a choice to smo from plain over branded packaging is important, so make it clause how these covariates were chosen. If BMJ Open permit it, it make this easier to understand for the reader, if the results from logistic regression (third paragraph of results section), were not to the statistical analysis section? Also, which covariates were	
which other analyses were conducted. Finally, why was having a smoking ad (p = 0.056) included as a covariate, when number cigarettes smoked per day (p = 0.098) was not? How were the covariates chosen? 2. The results section is not that well structured and it is hard reader to follow the analyses that have been conducted. Subheadings to introduce the participant characteristics, the logist regression on the differences between plain and branded passmokers and the different analyses that have been run would Also, the results from the ANCOVA are interspersed with the from the logistic regression. I am not clear about why the final section with the subheading 'Brand loyal cigarette smokers' is included, as this is not mentioned in the statistical analyses whereas all of the other analyses were. 3. Were there any differences observed between those indivisive reporting using plain packs at the beginning of the study (whe 57% were doing so, and therefore may have been those indivisions who sought out plain packs) and later on in the study (when 8 were doing so)? For example, were those using plain packs as the second plain packs and later on in the study (when 8 were doing so)? For example, were those using plain packs as the second plain plain plain	egression ces smoke tt clear it might s from the re moved vere ssion of aving seen umber of ethese ard for the sub- ogistic pack uld help. he results inal s' is s section, dividuals when only ndividuals en 85%

	4. P.9. Report all P-values, including those which are >0.05. (e.g. belief that the dangers of smoking had been exaggerated, quit
	intentions).
	5. Figure 1 should include a y axis label.
	6. Table 3, the final section about support for the new legislation
	should have the headings N(%)
	7. P.9. Reword the sentence 'Thus, effect sized eased slightly and
	significance levels dropped'.
	8. P.10. Should the percent of survey respondents smoking from
	plain packs at the end of the study be 85% rather than 80%, as this
	is the percent reporting smoking from plain packs in the last week?
GENERAL COMMENTS	I am generally positive about this paper which has important
	preliminary findings about the effect that new plain packaging
	legislation has had on smokers in Australia. However, I suggest a
	few revisions, which would greatly improve the clarity and impact of
	this important paper.
	1. In the abstract, make the last line of the results section clearer,
	such that it is obvious to the reader why 80% of respondents were
	smoking from plain packs (i.e. a bit more detail about the roll-out of the legislation).
	2. P.4. The third point of the 'article focus' section should be split into
	a number of sentences for clarity.
	3. P.5. Refer to the legislation as plain (preferably 'standardised')
	packaging, but not 'plainly' packaged.
	4. P.11. The third sentence of the third paragraph of the discussion
	should be reworded such that the smokers themselves are not
	described as plain or branded, but rather, the packs from which they
	smoke are plain or branded.
	5. P.11. With regard to smokers being accepting of health warning
	legislation, the percent of smokers endorsing the view that health
	warnings should be increased was only around 53%, which does not
	necessarily suggest that smokers are accepting of this aspect of the
	legislation, as suggested. Perhaps this sentence should be
	reworded to reflect this?

REVIEWER	Moodie, Crawford University of Stirling, Institute for Social Marketing
	No competing Interests
REVIEW RETURNED	22-May-2013

GENERAL COMMENTS	As the first empirical evidence to come from Australia, when plain packs were on the market, this paper will be of significant interest and merits publication. Some ideas to strengthen the paper are shared below:
	Abstract Pg 3, Ln 22: Change to 'frequency of thoughts of smoking harm in the past week'
	Pg 3, Ln 24: Omit 'from 0 (lowest) to 10 (highest)' as the response options are not provided for any other measure
	Pg 3, Lns 41-42: I think the authors need to clarify the sentence 'once 80% of survey respondents were smoking from plain packs' - this applies to mention of this in the Key Messages section of the Article Summary

Pg 3, Ln 46: 'Think about and prioritise quitting' seems a more accurate description than 'urgency to quit' – this applies to mention of urgency to quit in the Key Messages section of the Article Summary and elsewhere in the paper

Article Summary

Pg 4, Lns 10-13: What about non-experimental quantitative studies or studies employing the auction method? I think the authors should omit the information about all studies using experimental or qualitative approach and revise this sentence to read: 'Since no country had implemented plain packaging prior to Australia in 2012, all studies conducted to date have only simulated plain packaging'

Pg 4, Ln 17: There are three outcomes mentioned in lines 6-9 (appeal, harm, warning salience) but warning salience is not explored. As such, this should be revised as the wording suggests that you did examine these three 'outcomes'

Introduction

Pg 5, Ln 13: It would be helpful to know when the mass media TV campaign started and how long it ran for

Methods

The Methods and Results sections require sub-headings (e.g. Perceived Pack Quality and Satisfaction, Quitting, Policy Support, etc)

Pg 6, In 46: There is no issue with the question concerning what pack smokers were currently using, but one or two follow-up questions asking about whether plain packs had been used at all, and approximately how often, would have been informative. This could be included as an additional limitation or alternatively as a suitable direction for future research (even if not in Australia)

Pg 7, In 45: Use 'advertisements' rather than 'ads'

Pg 8, In 15: I think the use of 'current possession of a plain pack' should be used more frequently throughout the paper to reiterate that this is what was examined in this study

Pg 8, In 18: Remove 'ultimately'

Results

Pg 8, In 35: Clarify whether 'unbranded cigarettes' refers to illicit tobacco

Pg 9, Ins 4 and 11-14: There are multiple instances where non-significant differences are reported as if they are significant. If a p-value is 0.052 or 0.056, for instance, it is appropriate to talk about trends towards significance but otherwise they should be reported as non-significant; Table 3 identifies the OR and p-values for all measures

Pg 9, In 31-41: This paragraph requires revision. The authors need to be clearer rather than use terms such as 'additional adjustment' and 'caught up with'

Pg 9, In 46: Remove brackets before 'We'

Discussion

Pg 10, In 12: The subgroup smoking the same brand for the past year could be referred to as brand loyal smokers

Pg 10, Ins 26-30: Need to revise the comment about being the first study to assess the 'real world' impact of plain packaging, as a study in the UK published in this journal has attempted a 'real world' test. It would seem more accurate to state that this study differs from all others as it is the only study conducted in a market where plain packs are on the market. Other studies cannot properly evaluate plain packaging if it has not been introduced, but that does not mean that the findings are not relevant, particularly as this study does not appear to differ from the UK study previously mentioned or indeed studies using other designs with different samples and in different jurisdictions

Pg 10, In 44: As the authors refer to a mass media campaign postimplementation it would seem appropriate to also add that increased awareness of plain packaging may have been influenced by media coverage

Pg 11, lns 5-7: The avoidance of plain packs due to discomfort assertion is plausible but as this is not assessed in the study it should be omitted

Pg 11, In 13: The authors should be cautious about referring to the pattern of findings in respect to appeal and perceived harms as consistent with other research because the items on perceived harms were not significant

Pg 11, In 33: This sentence could be omitted or, at the very least, reworded

While the journal includes a section on Policy implications of a study, I think that the authors are correct not to include this

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

Reviewer: Olivia Maynard, PhD student Tobacco and Alcohol Research Group School of Experimental Psychology University of Bristol, UK

No competing interests.

1. P.8. The statistical analyses section is unclear and it is not easy to determine how the different analyses conducted (logistic regression and ANCOVA) relate to the results. Correcting for differences between individuals who have perhaps made a choice to smoke from plain over branded packaging is important, so make it clear how these covariates were chosen. If BMJ Open permit it, it might make this easier to understand for the reader, if the results from the logistic regression (third paragraph of results section), were moved to the statistical analysis section? Also, which covariates were ultimately chosen might be better placed before the discussion of which other analyses were conducted. Finally, why was having seen a smoking ad (p = 0.056) included as a covariate, when number of cigarettes smoked per day (p = 0.098) was not? How were these covariates chosen?

Author: We have revised the text in the Statistical analysis section of the Methods to make this

clearer. We now explain we used the conventional level of p<.25 as suggested by Hosmer & Lemeshow (2000), as a criterion for inclusion of covariates into the multivariate analyses. We moved the summary of the results of the testing of covariates to the Results section titled "Bivariate comparison of those smoking from branded and plain packs." We confirm that we did in fact include cigarette consumption as a covariate in all multivariate analyses (since those smoking 5-10 cigarette per day tended to be more likely (p=.098) than those who smoked <5 per day to be smoking from a plain pack). However, we inadvertently left this variable out of the summary list of covariates and have now included it. Thanks for picking this up.

2. The results section is not that well structured and it is hard for the reader to follow the analyses that have been conducted. Sub-headings to introduce the participant characteristics, the logistic regression on the differences between plain and branded pack smokers and the different analyses that have been run would help. Also, the results from the ANCOVA are interspersed with the results from the logistic regression. I am not clear about why the final section with the subheading 'Brand loyal cigarette smokers' is included, as this is not mentioned in the statistical analyses section, whereas all of the other analyses were.

Author: We have added additional sub-headings to the Results section, including "Participant characteristics", "Bivariate comparison of branded and plain pack smokers", and Multivariate comparison of branded and plain pack smokers". We do not think it is a problem to include the ANCOVA results in the Table with the logistic regression results, since each is clearly labelled. The final section of the Results on brand loyal smokers is a sensitivity analysis and we now make this clearer in the Statistical Analysis section of the Methods.

3. Were there any differences observed between those individuals reporting using plain packs at the beginning of the study (when only 57% were doing so, and therefore may have been those individuals who sought out plain packs) and later on in the study (when 85% were doing so)? For example, were those using plain packs at the start of the survey period more likely to respond positively to the question about their approval of plain packaging legislation?

Author: The results of Model 3, where we included survey week as a covariate, found its inclusion made no difference to the effect size for the outcome of approval of plain packaging. This means that survey week was unrelated to this outcome. We state in the results and discuss in the Discussion that only the appeal outcomes were related to survey week.

4. P.9. Report all P-values, including those which are >0.05. (e.g. belief that the dangers of smoking had been exaggerated, quit intentions).

Author: The detail of all statistical test outcomes is contained in Tables 2 and 3. We do not see a need to repeat all of them in the text.

5. Figure 1 should include a y axis label.

Author: We now include a label for the y-axis. We also took the opportunity to include colour in the graph, since this is permitted.

6. Table 3, the final section about support for the new legislation should have the headings N (%)

Author: We now include this information in Table 3.

7. P.9. Reword the sentence 'Thus, effect sizes eased slightly and significance levels dropped'.

Author: We reworded the sentence to: 'Thus, effect sizes eased slightly and significance levels declined'.

8. P.10. Should the percent of survey respondents smoking from plain packs at the end of the study be 85% rather than 80%, as this is the percent reporting smoking from plain packs in the last week?

Author: We do mean once 80% of smokers were smoking from plain packs. This occurred in the third week of November (not the last week). We have now added this timing of the third week of November to the text to prevent others from misunderstanding our meaning.

Reviewer 2.

I am generally positive about this paper which has important preliminary findings about the effect that new plain packaging legislation has had on smokers in Australia. However, I suggest a few revisions, which would greatly improve the clarity and impact of this important paper.

1. In the abstract, make the last line of the results section clearer, such that it is obvious to the reader why 80% of respondents were smoking from plain packs (i.e. a bit more detail about the roll-out of the legislation).

Author: We added 'when 80% of survey respondents were smoking from plain packs 1-2 weeks before the December implementation date' to the sentence to make this clearer.

2. P.4. The third point of the 'article focus' section should be split into a number of sentences for clarity.

Author: Now that we have made clearer what outcomes were examined, we do not think this is needed. We added another limitation which is: "Some smokers of branded packs may previously have smoked from a plain pack, which would be expected to reduce differences between plain and branded pack smokers."

3. P.5. Refer to the legislation as plain (preferably 'standardised') packaging, but not 'plainly' packaged.

Author: We revised the phrase to "be contained in plain packs".

4. P.11. The third sentence of the third paragraph of the discussion should be reworded such that the smokers themselves are not described as plain or branded, but rather, the packs from which they smoke are plain or branded.

Author: We made this revision.

5. P.11. With regard to smokers being accepting of health warning legislation, the percent of smokers endorsing the view that health warnings should be increased was only around 53%, which does not necessarily suggest that smokers are accepting of this aspect of the legislation, as suggested. Perhaps this sentence should be reworded to reflect this?

Author: We revised the sentence to describe the level of support as being a majority.

Reviewer 3.

Reviewer: Crawford Moodie

University of Stirling, Institute for Social Marketing

No competing interests

As the first empirical evidence to come from Australia, when plain packs were on the market, this paper will be of significant interest and merits publication. Some ideas to strengthen the paper are shared below:

Abstract

Pg 3, Ln 22: Change to 'frequency of thoughts of smoking harm in the past week'

Author: We retained the original phrasing because of the brevity imposed by the Abstract word limit.

Pg 3, Ln 24: Omit 'from 0 (lowest) to 10 (highest)' as the response options are not provided for any other measure

Author: We made this revision.

Pg 3, Lns 41-42: I think the authors need to clarify the sentence 'once 80% of survey respondents were smoking from plain packs' - this applies to mention of this in the Key Messages section of the Article Summary.

Author: We added 'once 80% of survey respondents were smoking from plain packs 1-2 weeks before the December implementation date' to the sentence to make this clearer.

in the Abstract and Key Messages section. As a result of these revisions, we also cut some existing words from the Abstract to meet the required word limit.

Pg 3, Ln 46: 'Think about and prioritise quitting' seems a more accurate description than 'urgency to quit' – this applies to mention of urgency to quit in the Key Messages section of the Article Summary and elsewhere in the paper

Author: We have adopted this more accurate language in the Key Messages section, and the Discussion section. We retained it in the Abstract since it is a practical way to summarise the overall effect observed in a shorthand form, as imposed by the Abstract word limit.

Article Summary

Pg 4, Lns 10-13: What about non-experimental quantitative studies or studies employing the auction method? I think the authors should omit the information about all studies using experimental or qualitative approach and revise this sentence to read: 'Since no country had implemented plain packaging prior to Australia in 2012, all studies conducted to date have only simulated plain packaging'

Author: We made this revision.

Pg 4, Ln 17: There are three outcomes mentioned in lines 6-9 (appeal, harm, warning salience) but warning salience is not explored. As such, this should be revised as the wording suggests that you did examine these three 'outcomes'

Author: We revised the point to make it clearer that perceptions of appeal and harm were the outcomes examined, plus thoughts about quitting.

Introduction

Pg 5, Ln 13: It would be helpful to know when the mass media TV campaign started and how long it ran for.

Author: We now add that the televised mass media campaign was aired throughout November.

Methods

The Methods and Results sections require sub-headings (e.g. Perceived Pack Quality and Satisfaction, Quitting, Policy Support, etc)

Author: We added sub-headings to the Results section, along the lines already suggested by Reviewer 1 and think this should be sufficient to aid readers.

Pg 6, In 46: There is no issue with the question concerning what pack smokers were currently using, but one or two follow-up questions asking about whether plain packs had been used at all, and approximately how often, would have been informative. This could be included as an additional limitation or alternatively as a suitable direction for future research (even if not in Australia)

Author: We think we already adequately acknowledge the limitations of using a designation of whether smokers are currently using a plain or branded pack in several paragraphs in the Discussion.

Pg 7, In 45: Use 'advertisements' rather than 'ads'

Author: We made this revision.

Pg 8, In 15: I think the use of 'current possession of a plain pack' should be used more frequently throughout the paper to reiterate that this is what was examined in this study

Author: We have revised and used this phrasing several times throughout the paper. We elected to retain the term plain and branded pack smokers when there was repetition in a paragraph and use of the more formal language read tediously.

Pg 8, In 18: Remove 'ultimately'

Author: We removed this word. The whole sentence has been moved to the Results section in the Bivariate analysis sub-section.

Results

Pg 8, In 35: Clarify whether 'unbranded cigarettes' refers to illicit tobacco

Author: We added a sentence in brackets in the text that "Unbranded tobacco is untaxed loose tobacco without any branding, sold in unmarked plastic bags."

Pg 9, Ins 4 and 11-14: There are multiple instances where non-significant differences are reported as if they are significant. If a p-value is 0.052 or 0.056, for instance, it is appropriate to talk about trends towards significance but otherwise they should be reported as non-significant; Table 3 identifies the OR and p-values for all measures

Author: We have revised our description of these particular findings using the language suggested in the Abstract, Key Messages section and in the Discussion section of the paper.

Pg 9, In 31-41: This paragraph requires revision. The authors need to be clearer rather than use terms such as 'additional adjustment' and 'caught up with'

Author: We added the term "additional covariate adjustment" to improve clarity of the first sentence. We revised the last sentence of that paragraph to read: "As the roll-out of plain packs reached 80% or more of smokers surveyed in the third week of November (1-2 weeks before the December

implementation date), the responses of branded pack smokers approached those of plain pack smokers."

Pg 9, In 46: Remove brackets before 'We'

Author: The reviewer may have overlooked that this sentence is purposefully enclosed in brackets at both ends.

Discussion

Pg 10, In 12: The subgroup smoking the same brand for the past year could be referred to as brand loyal smokers

Author: We now adopt this term in the first paragraph of the Discussion section.

Pg 10, Ins 26-30: Need to revise the comment about being the first study to assess the 'real world' impact of plain packaging, as a study in the UK published in this journal has attempted a 'real world' test. It would seem more accurate to state that this study differs from all others as it is the only study conducted in a market where plain packs are on the market. Other studies cannot properly evaluate plain packaging if it has not been introduced, but that does not mean that the findings are not relevant, particularly as this study does not appear to differ from the UK study previously mentioned or indeed studies using other designs with different samples and in different jurisdictions

Author: Our study is closer to a 'real world' test than any of these past studies because the "intervention" is not simply possession of a plain or branded pack, but the extent of roll-out of plain packs into the market more broadly, a feature that we have incorporated into the analysis and results and interpreted in the Discussion. Nevertheless, we have revised the wording to adopt the reviewer's suggestion and have additionally clarified that the previous studies (one published in BMJ Open and one in Tobacco Control) were "... naturalistic studies that have mocked-up plain packs for smokers to carry around with them in a trial situation.

Pg 10, In 44: As the authors refer to a mass media campaign post-implementation it would seem appropriate to also add that increased awareness of plain packaging may have been influenced by media coverage.

Author: We added a sentence to interpret the finding from the bivariate analyses that a greater proportion of those smoking from plain packs recalled the media campaign than those smoking from branded packs. In our view, this is likely to be because the new pack health warnings made the media campaign advertisements more salient or engaging. We included the following sentence along these lines: "The higher rate of recall of the mass media campaign among those with plain packs might be due to the accompanying large pack health warnings assisting the memorability or impact of the television messages, as has been found in past studies (Brennan et al 2011, Thrasher et al 2012)."

Pg 11, lns 5-7: The avoidance of plain packs due to discomfort assertion is plausible but as this is not assessed in the study it should be omitted.

Author: In making this interpretative comment, we took note of the results of the two Moodie et al naturalistic studies, which did find that those who carried around plain packs in their daily lives felt more ashamed, embarrassed and unaccepted about their packs, and had more negative feelings about smoking. We abbreviated this to 'uncomfortable'. We have now added two citations to these studies to support this interpretation.

Pg 11, In 13: The authors should be cautious about referring to the pattern of findings in respect to

appeal and perceived harms as consistent with other research because the items on perceived harms were not significant.

Author: We revised the sentence to be more cautious as follows: "The observed pattern of findings in relation to brand appeal and the direction of findings relating to perceived harms is consistent with those of experimental studies of plain packaging...."

Pg 11, In 33: This sentence could be omitted or, at the very least, reworded

Author: We don't see why this needs to be re-worded or omitted – it is an important point.

While the journal includes a section on Policy implications of a study, I think that the authors are correct not to include this.

Author: We think we have drawn appropriate conclusions.

VERSION 2 – REVIEW

REVIEWER	Olivia Maynard, Tobacco and Alcohol Research Group, School of Experimental Psychology, University of Bristol, UK.
	No competing interests.
REVIEW RETURNED	10-Jun-2013

GENERAL COMMENTS	I am now satisfied that the authors have addressed my previous
	comments about this manuscript.